

Attorney Docket No. 20720-95592

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Peter J. Manso
Name of person signing this paper or fee

October 15, 1999
Date


Signature of person signing this paper or fee

In re Application of: Dave Bova
Serial No.: 08/368,378
Filing Date: January 14, 1995
Group Art Unit: 1615
Batch No.: V45
Examiners: J. Venkat
Title: *Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor*

Box Issue Fee
Assistant Commissioner for Patents
Washington, D.C. 20231

**COMMENTS ON STATEMENT OF
REASONS FOR ALLOWANCE**

As the file history demonstrates, it is Applicant's position that Applicant has discovered unique methods for treating hyperlipidemia. The methods comprise administering to a hyperlipidemic an effective antihyperlipidemic amount of an oral nicotinic acid solid dosage form once per day, in the evening or at night.

Unlike the O'Neill et al., U.S. Patent No. 5,268,181, such unique methods, as claimed in claims 1-9 and 15-18, are accomplished without causing treatment limiting (i) hepatotoxicity, or (ii) without causing treatment limiting elevations in glucose and/or uric acid levels, or (iii) any combination thereof, in an appreciable number of subjects, irrespective of whether a hydrophobic

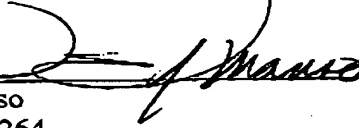
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component is mixed with the nicotinic acid prior to tablet or other product formulation. Thus, claims 1-9 and 15-18 are not limited to the requirement of adding a hydrophobic component for mixing with nicotinic acid prior to tablet formulation, as suggested by the Examiner in paragraph 1 of the Notice of Allowance mailed on July 7, 1999 in connection with the above-identified application for U.S. patent.

Respectfully Submitted,

Date: October 15, 1999


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